

-23-

What is claimed is:

1. An assembly for forming a barrel of a pre-filled syringe, comprising:

5 (a) a syringe body having a generally cylindrical side wall with an inner surface and an outer surface, the side wall extending between a neck end and a rimmed end;

10 (b) a generally cylindrical elastomeric piston having an upper surface, a side surface adapted to form a hermetic seal with the inner surface of the cylindrical side wall when inserted into the open rimmed end of the syringe body, and a lower surface opposite the upper surface;

15 (c) a generally cylindrical sleeve having a base end and a top end, wherein said syringe body is received inside the top end of the sleeve in a close fit with the rimmed end of the syringe body located intermediate the top end and the base end of the sleeve;

20 (d) piston support means in contact with the sleeve, said piston support means having a support surface on which the piston is supported with its upper surface spaced from the rimmed end of the syringe body and substantially concentric therewith, such that a gap exists between the upper surface of the piston and the rimmed end of the syringe body, thereby permitting sterilization of the syringe body and the piston by a
25 sterilizing gas.

30 2. The assembly of claim 1, wherein the base end of the sleeve has an outer diameter sufficient to permit the assembly to be conveyed standing upright through an apparatus for filling and capping pharmaceutical vials.

-24-

3. The assembly of claim 1, wherein the base end of the sleeve has an outwardly projecting flange, the flange having a diameter and a height so as to prevent interference such as would cause tipping when the assembly is conveyed standing upright through an apparatus for filling and capping pharmaceutical vials.

4. The assembly of claim 3, wherein the flange has a substantially flat radially outwardly facing wall which is substantially vertical when the assembly is standing upright.

5. The assembly of claim 1, wherein the sleeve has an inwardly projecting portion intermediate the base end and the top end for supporting the rimmed end of the syringe body.

6. The assembly of claim 5, wherein the inwardly projecting portion comprises a detent of sufficient shape and size to retain the rimmed end of the syringe body intermediate the top end and the base end of the sleeve in the absence of a force which pushes the rimmed end of the syringe body and the base end of the sleeve toward one another, but which permits the rimmed end and the base end to be pushed toward one another in response to a predetermined force.

7. The assembly of claim 1, wherein the piston support means is integrally formed with the sleeve, and comprises a piston support surface located radially inwardly of the inner surface of the syringe body side wall.

8. The assembly of claim 7, wherein the piston support surface is annular with a central aperture through which the piston can be engaged by a plunger.

9. The assembly of claim 8, wherein the piston support surface is positioned

-25-

relative to the base end of the sleeve such that the piston is supported above the base end of the sleeve when the assembly is standing upright.

10. The assembly of claim 9, wherein the piston support surface is spaced inwardly from the inner surface of the sleeve by a distance substantially equal to a thickness of the syringe body side wall, thereby forming an annular recess between the piston support surface and the inner surface of the sleeve, the annular recess having a bottom wall intermediate the piston support surface and the lower surface of the base end, such that when a force is applied to push the rimmed end of the syringe body into the annular recess until it engages the bottom wall, the piston becomes fully inserted in the syringe body with its side surface forming a hermetic seal with the syringe body side wall.

11. The assembly of claim 1, wherein the piston support means comprises a stabilization cap comprising a hollow cylindrical portion with an upper end and a lower end adapted to fit inside the syringe body, with the upper end of the cylindrical portion forming a piston support surface for engagement with the lower surface of the piston, the stabilization cap further comprising a finger flange projecting radially outwardly at the lower end of the adapter ring.

12. The assembly of claim 11, wherein the finger flange fits inside the base end of the sleeve.

13. The assembly of claim 1, wherein a plurality of said piston support means are arranged on a tray.

14. The assembly of claim 7, wherein said a plurality of said integrally formed sleeves and piston support means are arranged on a tray.

15. A method for producing a pre-filled syringe body for a pre-filled syringe, the

-26-

syringe body comprising a barrel and a piston, the barrel having a generally cylindrical side wall with an inner surface and an outer surface, the side wall extending between a neck end and a rimmed end of the barrel, the piston being generally cylindrical and formed of an elastomeric material with an upper surface, a side surface adapted to form a hermetic seal with the inner surface of the barrel when inserted into the open rimmed end of the barrel, and a lower surface opposite the upper surface, the method comprising:

- (a) forming a first assembly comprising said elastomeric piston, a generally cylindrical sleeve having an inner surface, and outer surface, a base end and a top end, and piston support means in contact with the sleeve and having a piston support surface on which the piston is supported with its lower surface engaging the piston support surface, the piston support surface being spaced radially inwardly of the inner surface of the sleeve;
- (b) forming a second assembly by inserting the rimmed end of the barrel into the top end of the sleeve to a sufficient depth that the barrel is stably supported in the sleeve, and such that the rimmed end is located intermediate the top end and the base end of the sleeve with a gap between the upper surface of the piston and the rimmed end of the barrel;
- (c) sterilizing the second assembly with a sterilizing gas;
- (d) applying a force to the second assembly to cause relative movement of the barrel toward the base end of the sleeve, causing insertion of the piston into the barrel such that the side surface of the piston forms a hermetic seal with the inner surface of the barrel and seals the rimmed end of the barrel;

-27-

(e) filling said barrel with a medicament or a component thereof through the neck end using equipment for filling and capping pharmaceutical vials; and

5 (f) capping the neck end of the barrel using said equipment for filling and capping pharmaceutical vials;

wherein, subsequent to insertion of the piston in step (d), said second assembly is conveyed through at least a portion of said equipment for filling and
10 capping pharmaceutical vials while freestanding in an upright position.

16. The method of claim 15, wherein the medicament is in the form of a liquid when filled into the barrel in step (e), and wherein the method further comprises lyophilization of the medicament between steps (e) and (f).

17. The method of claim 15, wherein the sleeve is removed from the syringe body after step (f).

18. The method of claim 17, wherein the pre-filled syringe body further comprises an adapter ring which forms said piston support means and comprises a hollow cylindrical portion with an upper end and a lower end, the upper end of the hollow cylindrical portion forming a piston support surface for engagement with the lower surface of the piston, the adapter ring further comprising a finger flange projecting radially outwardly at the lower end of the adapter ring, and wherein during step (d) the hollow cylindrical portion of the adapter ring becomes received inside the barrel, with the rimmed end of the barrel engaging the finger flange.

19. The method of claim 18, wherein the cylindrical portion of the adapter ring forms a snap fit with the rimmed end of the barrel.